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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,219	07/07/2003	Christoffer Bro	BRO1	7056
1444 7590 02/27/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER SCHLAPKOHL, WALTER	
			ART UNIT 1636	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/27/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/613,219		BRO ET AL.	
	Examiner		Art Unit	
	Walter Schlapkohl		1636	<i>maf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) 15-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-6 and 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the papers filed 11/22/2006 in which claims 1-2, 4-6 and 8-12 were amended, claims 13-25 were added, and claim 3 was cancelled. Claims 1-2, 4-6 and 8-25 are pending. Claims 15-25 are withdrawn. Claims 1-2, 4-6 and 8-14 are under examination in the instant Office action.

Any rejection of set forth in the previous Office action not recited herein is hereby withdrawn.

Election/Restrictions

Newly submitted claims 15-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally claimed invention and the newly claimed invention are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the originally claimed fungal

cell can be used to produce ethanol, lactic acid, citric acid or for the production of recombinant PGM2 itself.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

However, where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected

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product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-6 and 8-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record and extended to new claims 13-14.**

Claims 1-2, 4-6 and 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for wild type PGM2 in *S. cerevisiae*, does not reasonably provide enablement for any recombinant, prototrophic fungus comprising any PGM2 enzyme. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. **This rejection is maintained for reasons of record and extended to new claims 13-14.**

Response to Arguments

Applicant argues that the claims as amended are limited to PGM2, an enzyme of completely known structure. Applicant further argues that the biochemical pathway which is being manipulated in the current invention is a fundamental one common to fungi in general. Applicant further argues that Examiner has

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imposed an improper standard, wherein Examiner states that the example of the invention in the specification is "not necessarily predictive" of any other enzyme besides wild type PGM2 capable of catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate. Applicant further argues that Examiner has "put forward no specific reason why the invention should not operate in other yeasts, and other fungi in general" (see page 8, last full paragraph of the Remarks filed 11/22/2006). For the same reasons, Applicant submits that both the written description rejection and the enablement rejection should be withdrawn.

Examiner has considered Applicant's arguments carefully and has respectfully found them unpersuasive. Examiner notes that while Applicant's claims are now limited to microorganisms overexpressing "PGM2", Applicant's claims encompass any PGM2 sequence including any "mutated form" which "mutated form has a higher specific activity than the native form" of the enzyme (see page 6, 1st paragraph of the specification). Furthermore, as explained in the previous Office action, the prior art demonstrates that while at least four enzymes (AGM, PGM1, PGM2 and PMM) were known to catalyze the conversion of glucose-1 phosphate to glucose-6 phosphate in the galactose metabolic pathway, these enzymes have "partially overlapping substrate

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specificities but distinct physiological functions" (Hofmann et al, *European Journal of Biochemistry* **221**:741-747, 1994; cited previously). Moreover, the specification teaches that galactose is first transported into the cell by a specific permease (page 2, 1st full paragraph). In addition galactose uptake occurs via facilitated diffusion. Thus, although Examiner agrees with Applicant insofar as the biochemical pathway which results in the conversion of glucose-1 phosphate to glucose-6 phosphate is, in a very general sense, common to most, if not all fungi, the exact mechanism for the observed increase in galactose uptake rate in Applicant's claimed recombinant microorganisms is unknown. Furthermore, neither the specification nor the prior art form a nexus between PGM2 and GAL2 function such that one of ordinary skill in the art would know which functions of PGM2 are required such that galactose uptake rate is increased. It is therefore unclear which domains and/or sequences of such enzymes generally and of PGM2 in particular would be responsible for Applicant's observed increase in galactose uptake rate in PGM2-overexpressing *S. cerevisiae*. Furthermore, because neither the prior art nor the specification teach which domains/sequences of PGM2 besides those of wild-type PGM2 are required to construct a microorganism with an increased galactose uptake rate, Applicant still has not described the claimed invention in such a way as

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to convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, i.e mutated forms of PGM2 with higher specific activity than the native form. Applicant's argument with regard to the standard applied by Examiner is not found persuasive because such a "standard" is appropriately applied in light of the written description analysis which includes consideration of the disclosure of a complete, or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation and any combination thereof that would convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is further noted that the "standard" highlighted by Applicant is only one consideration among many made in the rejection of the claims under 35 U.S.C. 112, First Paragraph. This is in contrast to Applicant's argument that Examiner has "put forward no specific reason why the invention should not operate in other yeasts, and other fungi in general" wherein Applicant has inappropriately applied a standard of *operability* when the correct (and applied) analysis for the rejection of claims under 35 U.S.C. 112, First Paragraph (written description) is that of *possession*. Examiner has addressed the considerations germane

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to a rejection under 35 U.S.C. 112, First Paragraph as they concern possession and enablement (including the Wands factors), none of which include operability.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

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(December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all

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For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

February 8, 2007


DAVID GUZO
PRIMARY EXAMINER